

Message Text

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DRAFTED BY DHEW/FDA:JRWEINROTH

APPROVED BY SCI:MSBEAUBIEN

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TO AMEMBASSY BONN

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E.O. 11652: N/A

TAGS: EAGR, TBIO, GW

SUBJECT: REQUEST FOR PUBLICATION

REF: BONN, 02424, FEBRUARY 13, 1974, TOFAS 46

BONN, 04992, MARCH 28, 1974, TOFAS 105

1. REGARDING GERMAN MINISTRY OF HEALTH REQUEST FOR PUBLICATIONS CONCERNING STATEMENT OF CONSENT BY OR FOR PERSONS TO WHOM DRUGS ARE ADMINISTERED FOR CLINICAL TESTING, FDA'S OFFICE OF INTERNATIONAL AFFAIRS AIR MAILING FOLLOWING DOCUMENTS TO EMBASSY:

1. DHEW - NIH - PROTECTION OF HUMAN SUBJECTS POLICIES AND PROCEDURES - FROM FEDERAL REGISTER VOL. 38, NO. 221, NOVEMBER 16, 1973.

2. XEROX PART 130.37 21 CFR - CONSENT FOR USE OF INVESTIGATIONAL NEW DRUGS (IND) ON HUMANS, STATEMENT OF POLICY.

3. (A) 3 FORMS FD 1571 - NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION FOR A NEW DRUG.

(B) 3 FORMS FD 1572 - STATEMENT OF INVESTIGATOR (CLINICAL PHARMACOLOGY)

(C) 3 FORMS FD 1573 - STATEMENT OF INVESTIGATOR.

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(D) REPRINT - ASSURING SAFE AND EFFECTIVE DRUGS.

(E) REPRINT - CLINICAL TESTING FOR SAFE AND EFFECTIVE DRUGS.

2. DELAY IN REPLY TO REQUEST OCCASIONED BY MISROUTING TELEGRAMS
TO DEPARTMENT OF AGRICULTURE AND NOT TO DEPARTMENT, HEALTH
EDUCATIONS AND WELFARE/FOOD AND DRUG ADMINISTRATION.
KISSINGER

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Message Attributes

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